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Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Avenue, S. W. Room 615F
Washington, D.C. 20201

Dear Secretary Shalala:

I am a board certified, state licensed hearing instrument specialist. For over 12 years I have provided hearing health care service to thousands of people in the State of Pennsylvania. For the past 5 years I have operated a small business in Lancaster County.

Currently, hearing instrument specialists, physicians and audiologists are fully qualified entry levels into the hearing health care system. The FDA is planning to allow the states to choose which hearing health care providers are qualified entry levels into the hearing health care system. If the FDA defers to the states this will create confusion and inconsistency in our nation. The audiologists have indicated that they will launch a 50 state effort to install themselves as the sole entry level into hearing health care without any medical or health policy justification.

Hearing impairment is a major health care concern. According to the AARP only 20% of the 28 million hearing-impaired Americans who could benefit from a hearing aid actually have one. Ironically, the proposed FDA rule would be an obstacle to the access of needed hearing health services to my clients and millions of other hearing-impaired Americans, and it will increase the cost to the hearing-impaired.

Currently, my business provides service and hearing tests to two thousand patients twice a year. My business also provides 5 employees with full time employment, and full health care benefits for them and their families. Please take the time to consider the impact of this proposed hearing aid rule on America's hearing-impaired, and on small businesses that provide hearing health care.

Please do not allow the FDA to propose a rule that would establish barriers and raise the cost of hearing health service to millions of Americans.

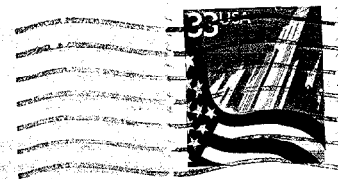
Sincerely,

Patrick Leedy, BC-HIS

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